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09/483,184	01/14/2000	Ruth W. Craig	DART1110-1	8067

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Gray Cary Ware & Freidenrich LLP
Suite 1600
4365 Executive Drive
San Diego, CA 92121-2189

EXAMINER	
CANELLA, KAREN A	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 02/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/483,184	CRAIG ET AL.	
	Examiner	Art Unit	
	Karen A Canella	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) 1-9 is/are allowed.

6)☐ Claim(s) 10,14,20 and 21 is/are rejected.

7)☐ Claim(s) 11-13 and 15-19 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 9, 18, 20 and 21 have been amended. Claims 1-21 are pending and under consideration

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

3. The rejection of claims 20 and 21 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained. Claim 20 is drawn to a genus of oligonucleotides comprising at least ten nucleotides which hybridize to residues comprising three nucleotides 5' and three nucleotides 3' of residues 2414, 2766, 3013 and 3786 of SEQ ID NO:1. It is noted that the claim requires the at least ten nucleotides to hybridize, but does not require the hybridization of the oligonucleotide as a whole to SEQ ID NO:1. Thus any nucleic acid sequence which minimally comprises ten contiguous nucleic acids which would hybridize to the recited sequence locations within SEQ ID NO:1 would belong to the claimed genus. Claim 21 is drawn to an oligomer which specifically hybridizes to residues 2412-2414 of SEQ ID NO:1 operably linked and contiguous to nucleotides 3768-3770 of SEQ ID NO:1. Thus, claim 21 reads on any nucleic acid sequence minimally comprising a polynucleotide sequence of nucleotides 2412-2414 of SEQ ID NO:1 contiguous with nucleotides 3768-3770 of SEQ ID NO:1 wherein the polynucleotide is at least 10 nucleotides. It is again noted that only the 10 nucleotides carry the limitation of hybridizing to the specified regions of SEQ ID NO:1. Thus, claims 20 and 21 are drawn to a genus of oligonucleotides. The genus of oligonucleotides of claim 20 and claim 21 are not limited by functional attributes, any nucleic acid having the minimum structural requirements would belong in the genus. The genus is also variant in terms of structure because only ten nucleotides need to be taken from SEQ ID NO:1 in order to satisfy the requirement of belong to the genus. The disclosure of SEQ ID NO:1, or the polynucleotides encoding SEQ ID NO:3 do not anticipate these genuses because the genuses are highly variant. One of skill in the art would conclude that applicant did not describe an adequate number of

species to describe the claimed genuses and therefore was not in possession of the invention. Further, the art teaches other nucleic acid sequences which are members of the claimed genuses but have not been disclosed by the specification (see the art rejections below). One of skill in the art would conclude that applicant was not in possession of the claimed genus.

4. Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by any Fu et al (CA 2,241,726, abstract), Nishina et al (WO 97/38004, abstract), Georgopoulos (WO 94/06814, abstract) or Fioretti et al (WO 95/23237, abstract). Claim 21 is drawn to an oligonucleotide comprising at least ten nucleotides that hybridize specifically to a nucleotide sequence of SEQ ID NO:1 comprising nucleotides 2412-2414 contiguous with nucleotides 3768-3770, or a polynucleotide complementary thereto wherein said polynucleotide comprises at least ten nucleotides. Nucleotides 2412-2414 of SEQ ID NO:1 are "AAG". Nucleotides 3768-3770 of SEQ ID NO:1 are "GAT". A oligonucleotide must therefore comprise "AAGGAT" in addition to four other contiguous residues of SEQ ID NO:1 order to satisfy the claim limitation of a polynucleotide complimentary thereto.

Fu et al disclose the oligonucleotide GAAAGGATGGGTGTGTATTCAGG. Nucleotides 3-12 of Fu et al are residues 2412-2414 of SEQ ID NO:1 fused to residues 3768-3775 of SEQ ID NO:1. The oligonucleotide of Fu et al comprises ten nucleotides which are a polynucleotide complementary to the oligonucleotide which specifically hybridize to the recited regions of SEQ ID NO:1.

Nishina et al disclose the oligonucleotide GTCCAAGGATGGAGACCT. Nucleotides 4-13 of Nishina et al are residues 2410-2414 of SEQ ID NO:1 fused to residues 3768-3772 of SEQ ID NO:1.

Georgopoulos discloses the oligonucleotide of AGGCGCCATTCCAAGGATAACACC. Nucleotides 9-18 of Nishina et al are residues 2410-2414 of SEQ ID NO:1 fused to residues 3768-3770 of SEQ ID NO:1.

Fioretti et al discloses the oligonucleotide ACTGATGTTCTTCCAAGGATGTGGG. Nucleotides 11-20 of Fioretti et al are residues 2410-2414 of SEQ ID NO:1 fused to residues 3768-3770 of SEQ ID NO:1.

5. Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by the abstract of LeCuyer et al (PNAS, 1994, vol. 91, pp. 3373-3377) , Lopez-Nieto et al (WO 95/31574, abstract), the abstract of Fisher et al (Nucleic acids Research, 1984, Vol. 12, pp. 3295-3302), the abstract of Saiki et al (New England Journal of Medicine, 1988, vol. 319, pp. 537-541), the abstract of Ellar et al (US 4,918,006), the abstract of Cech et al (Nucleosides and Nucleotides, 1988, Vol. 7, pp. 585-588), the abstract of Kroeger et al (Nature, 1982, Vol. 297, pp. 15-162) and the abstract of Crea et al (PNAS, 1978, vol. 75, pp. 5765-5769).

Claim 20 is drawn in part to an oligonucleotide comprising at least ten nucleotide that hybridize specifically to a nucleic acid sequence of comprising nucleotide position 2414 of SEQ ID NO:1 wherein at least three nucleotides of said oligonucleotide hybridize to a nucleotide sequence of SEQ ID NO:1 that is 5' and contiguous to said nucleotide position and wherein at least three nucleotides of said oligonucleotide hybridize to a nucleotide sequence of SEQ ID NO:1 that is 3' and contiguous to said nucleotide position, or a polynucleotide complementary to said oligonucleotide, wherein the polynucleotide is at least ten nucleotides. Kroeger et al disclose the polynucleotide of CAAGGTAAGAA which is residues 2411-2421, and therefore is a polynucleotide complementary to the oligonucleotide which would specifically hybridize to residues of 2411-2421. Crea et al disclose the polynucleotide AACAAGGTACAA which is residues 2409-2420 of SEQ ID NO:1 and therefore a polynucleotide which is complementary to the olgionucleotide which would specifically hybridize to residues 2409-2420 of SEQ ID NO:1.

Claim 20 is drawn in part to an oligonucleotide comprising at least ten nucleotide that hybridize specifically to a nucleic acid sequence of comprising nucleotide position 2766 of SEQ ID NO:1 wherein at least three nucleotides of said oligonucleotide hybridize to a nucleotide sequence of SEQ ID NO:1 that is 5' and contiguous to said nucleotide position and wherein at least three nucleotides of said oligonucleotide hybridize to a nucleotide sequence of SEQ ID NO:1 that is 3' and contiguous to said nucleotide position, or a polynucleotide complementary to said oligonucleotide, wherein the polynucleotide is at least ten nucleotides. Ellar et al disclose the polynucleotide of AAACAGGCATC which is residues 2770-2780 of SEQ ID NO:1, and therefore is a polynucleotide which is complementary to the oligonucleotide which specifically hybridizes to residues 2770-2780 of SEQID NO:1. Cech et al disclose the oligonucleotide of AATGCCTGGCATT which would specifically hybridize to residues 2768-2780 of SEQ ID

NO:1 as well as the polynucleotide of AATGCCAGGCATT which is residues 2768-2780 of SEQ ID NO:1 and therefore a polynucleotide complementary to the disclosed oligonucleotide.

Claim 20 is drawn in part to an oligonucleotide comprising at least ten nucleotide that hybridize specifically to a nucleic acid sequence of comprising nucleotide position 3073 of SEQ ID NO:1 wherein at least three nucleotides of said oligonucleotide hybridize to a nucleotide sequence of SEQ ID NO:1 that is 5' and contiguous to said nucleotide position and wherein at least three nucleotides of said oligonucleotide hybridize to a nucleotide sequence of SEQ ID NO:1 that is 3' and contiguous to said nucleotide position., or a polynucleotide complementary to said oligonucleotide, wherein the polynucleotide is at least ten nucleotides. Fisher et al disclose the polynucleotide of GGCGGGCTGGGTATC which is residues 3064-3078 of SEQ ID NO:1, and therefore is a polynucleotide which is complementary to the oligonucleotide which specifically hybridizes to residues 3064-3078 of SEQ ID NO:1. Saiki et al disclose the polynucleotide of CTGGGTATTAGTCTA which is residues 3070-3084 of SEQ ID NO:1, and therefore is a polynucleotide which is complementary to the oligonucleotide which specifically hybridizes to residues 3070-3084 of SEQID NO:1.

Claim 20 is drawn in part to an oligonucleotide comprising at least ten nucleotide that hybridize specifically to a nucleic acid sequence of comprising nucleotide position 3786 of SEQ ID NO:1 wherein at least three nucleotides of said oligonucleotide hybridize to a nucleotide sequence of SEQ ID NO:1 that is 5' and contiguous to said nucleotide position and wherein at least three nucleotides of said oligonucleotide hybridize to a nucleotide sequence of SEQ ID NO:1 that is 3' and contiguous to said nucleotide position or a polynucleotide complementary to said oligonucleotide, wherein the polynucleotide is at least ten nucleotides. LeCuyer et al disclose the polynucleotide of GTTCTTCAAA, which is residues 3782-3791 of SEQ ID NO:1 and therefore is a polynucleotide which is complementary to the olgionucleotide which specifically hybridizes to residues 3782-3791 of SEQ ID NO:1. Lopez-Nieto et al disclose the polynucleotide of CCTTCTTCAT which is residues 3781-3790 of SEQ ID NO:1, and therefore is a polynucleotide which is complementary to the oligonucleotide which specifically hybridizes to residues 3781-3790 of SEQ ID NO:1.

6. The rejection of claims 10 and 14 under 35 U.S.C. 102(b) as being anticipated by The New England Biolabs Catalog (1993-1994, page 91) is maintained for reasons of record. The New England Biolabs Catalog discloses random hexamers which are complementary to the polynucleotides encoding an Mcl-1 polypeptide or the Mcl-1s/deltaTM sequence.

Applicant argues that the hexamers do not satisfy the claim limitations because they are not at least ten nucleotide in length. This is not persuasive for claim 10 and 14 because said claims do not contain a size limitation for the "polynucleotide complementary thereto". The size of the random oligonucleotides was chosen to be a 6-mer in order that they may be complementary to generic nucleic acids. Without a limitation as to the length of the polynucleotide complementary thereto which would be greater than a 6-mer, the rejection is maintained.

7. Claims 11-13 and 15-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. All other rejections and objections as set forth in the previous Office action are withdrawn.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (571) 272-0828. The examiner can normally be reached on Monday through Friday from 9 am to 6:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (571) 272-0871. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at 703-308-4357.

Karen A. Canella, Ph.D.
Primary Examiner, Group 1642 Karen A. Canella
01/25/04